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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,304	07/19/2006	John P. Morseman	2997-74-PUS	9086

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1628	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,304	MORSEMAN ET AL.	
	Examiner	Art Unit	
	JENNIFER M. KIM	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *124-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *124-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/30/10;12/21/09;11/16/09;9/30/09;7/19/06.

DETAILED ACTION

The amendment filed June 6, 2010 have been received and entered into the application.

Applicants' election without traverse of claims drawn to a method to treat a Reelin deficiency or dysfunction, comprising administering to a patient diagnosed with or suspected of suffering from schizophrenia comprising administering an ester of DHA is acknowledged. Applicants' newly added claims 124-136 read on the elected Group, therefore, the claims are being examined in this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 124-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to the phrase "**suspected** of suffering" set forth in claim 124 is unclear because one of ordinary skill in the art would not be able to determine a subject population as a "suspect" suffering schizophrenia without clear demographic data or criteria to determine a 'suspect' from a 'non-suspect'. Therefore, one of ordinary skill in the art would not be able to practice the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 124-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin (U.S.Patent No. 4,977,187) in view of Fatemi (WO 03/063110A1, herein refer

to Fatemi (WO)) of record and Fatemi et al. (Neurophysiology, basic and clinical, NeuroReport, 2001, herein refer to Fatemi (2001)) of record.

Horrobin teaches method of treating schizophrenia comprising administration of a pharmaceutical composition comprising 300mg DHA in a capsule form taken 2 to 10 per day (abstract, column 6, lines 55-65). These amounts overlap and touch Applicants' daily amounts set forth in claims 125-127. Horrobin teaches that salts and esters of EFAs including DHA can be employed (column 5, lines 3-5).

Horrobin does not teach the steps of obtaining a biological sample detecting the amount of Reelin and comparing with the control sample in a schizophrenic patients set forth in claims 124,132-135; the percentage amount of DHA set forth in claims 130 and 131; duration of therapy set forth in claim 128; and the second therapeutically effective amount of ester of DHA greater than the therapeutically effective amount set forth in claim 136.

Fatemi (WO) teaches the methods and materials that can be used to facilitate diagnosis of psychiatric condition including schizophrenia which facilitate the diagnosis of psychiatric conditions and thereby improve therapy decisions and patient outcomes. Fatemi (WO) teaches that psychiatric conditions such as schizophrenia can decrease the life quality of affected persons and can present a risk of harm to those affected and to others. Fatemi (WO) teaches that psychiatric disorders are complicating matter having different causal elements and different treatment protocols that have confusingly similar clinical symptoms (abstract, pages 1 and 2).

Fatemi (WO) teaches the use of Reelin as a marker for diagnosing psychiatric conditions. Fatemi (WO) teaches that Reelin is disclosed as tools and techniques facilitate the diagnosis of psychiatric disorders including schizophrenia because Reelin levels are reportedly altered in the brains of some humans afflicted with schizophrenia suggesting that Reelin may be involved in cell signaling systems underlying brain cognitive functions. Fatemi (WO) teaches that the levels of Reelin moieties in biological samples can be determined using an immunoassay (e.g. ELISA) that employs monoclonal or polyclonal antibodies to capture Reelin moieties (abstract, pages 1-3, claims).

Fatemi (WO) teaches various of method of making diagnosis of schizophrenia can be made including the level of a Reelin moiety having apparent molecular mass of about 410kDa is increased relative to control subjects, and the level of a Reelin moiety having an apparent molecular mass of about 180 kDa is not different from or is decreased relative to control, subjects. A diagnosis of schizophrenia also can be made if the level of a Reelin moiety having an apparent molecular mass of about 330 kDa is increased relative to control subjects (page 3).

Fatemi (WO) teaches that in general, the level of a Reelin moiety in a biological sample (e.g. whole blood, plasma and serum) from a patient can be determined and compared with the level to that of one or more control subjects (page 7). Fatemi (WO) illustrates the steady state serum levels of Reelin moieties, Albumin and ceruloplasmin in schizophrenic patients and control patients (page 16).

Fatemi (2001) teaches that Reelin is a secreted extracellular matrix protein 410kDa mol. Wt. that is reduced in brains of patients with schizophrenia (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the DHA composition of Horrobin for the treatment of schizophrenia in a patient who has been diagnosed with having schizophrenia by steps of obtaining a biological sample of Reelin and comparing the amount of Reelin in the biological sample with the control sample set forth in claims 124 and 132 because that Horrobin teaches that DHA composition and its effective amounts for the treatment of schizophrenia and because that the diagnostic steps of schizophrenia set forth in claims 124 and 132 are well known in the art to facilitate diagnosis of psychiatric conditions in view of Fatemi (WO). One would have been motivated to make such a modification in order to increase the life quality of affected person and avoid a risk of harm to those affected and to others and properly treated with an effective agent such as DHA. There is a reasonable expectation of successfully identify and/or diagnose and treat schizophrenia by employment of Fatemi's tools and techniques and Horrobin's DHA composition because those tools and techniques of Fatemi can facilitate the diagnosis of schizophrenia and thereby improve therapy decision and patient outcomes; and because DHA composition effective for the treatment of schizophrenia is old and well known by Horrobin.

The limitation in claims 124 and 132, that an ester of DHA to the patient "compensate" for the effect of Reelin deficiency or dysfunction (schizophrenia) is noted. However, such is obvious because DHA is effective for the treatment of schizophrenia,

therefore, upon the treatment of schizophrenia with an active agent, DHA, that is effective for the treating the disease, any lab findings or exhibition of biological levels characterizing the disease such as Reelin level would obviously be compensated. Given that the Reelin is reduced in brains of patients with schizophrenia is known in the art in view of Fatemi (2001), it is obvious upon the treatment of the disorder with the active agent that is effective for the treatment of schizophrenia, Reelin level would be compensated back to normal. The amounts of active agents DHA to be used "at least 70%" of DHA and adjustment of the dosages so that the second amount to be administered is greater than the first depends on the prognosis of the disease and patient's medical status, the composition formulations, e.g., pharmaceutical, dietary, food supplement, etc; duration of therapy to treat a disease, and the duration of time to take the next biological sample to determine the prognosis are all deemed obvious since they are all within the knowledge of the skilled artisan and represent conventional formulations and modes of administration. Therefore, the claimed invention, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

None of the claims are allowed.

Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1628

Jmk
August 11, 2010